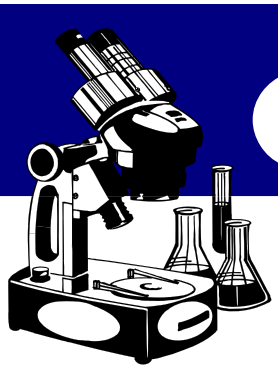

CLIA BITS

North Dakota Department of Health
Division of Health Facilities Spring 2008

CLIA Quality Systems Assessment (Part 4 of a continuing series) Postanalytic Systems – 493.1290-493.1299

Postanalytic Systems is the last of four quality systems. Postanalytic Systems includes laboratory activities related to the reporting of patient test results. The laboratory must establish a system to ensure test results are accurately and reliably sent from the testing site to the final report destination.

Requirements for the test report include:

- Positive patient identification – patient's name and identification number or unique patient identifier and identification number.
- Name and address of the laboratory location where the testing was performed.
- Test report date.
- Test performed.
- Specimen source, when appropriate.
- Test result and units or measurement or interpretation.
- Disposition of unacceptable specimens.

The laboratory's reference intervals or normal ranges must be available to the authorized ordering individual. The laboratory's clients must be provided updates on testing information whenever test changes occur that affect the test results or interpretation of results.

If laboratory results are considered panic values or critical values, the laboratory must notify the ordering individual immediately. The date, time, test results and person notified should be documented in the laboratory records.

If delays in patient testing have the potential to impact patient care negatively, the laboratory must notify the ordering individual.

If errors in patient test results are discovered, the laboratory must do the following:

- Promptly notify the ordering individual of the error.
- Issue a corrected report.
- Maintain copies of the original report and the corrected report.

Postanalytic systems areas to consider monitoring include:

- Patient information included on the test report.
- Normal ranges and units of measurement included on the test report.
- Legibility of the test report and results.
- Turn-around times for routine and STAT tests.

(Continued on page 2)

Inside this Issue:

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- Critical or panic values are defined.
- Documentation of notification of critical results.
- Verification of accuracy of calculated results.
- Alternative methods for reporting results if the laboratory information system is inoperable.
- Security of the reporting system (e.g., facsimile, remote printers, laboratory information system).
- Reports received from the referral laboratory are complete, accurate and timely.
- Results are transcribed accurately from instrument print outs or logbooks to the patient report.
- Results from interfaced instruments are downloaded accurately.

Postanalytic quality assessment includes monitoring issues related to the test report. Is your laboratory delivering a quality product to its customers?

Quality assessment is an ongoing process covering all functions of the laboratory. If your laboratory is monitoring the same areas year after year and meeting the acceptable criteria, consider exploring new areas to monitor. Make sure your laboratory is monitoring general laboratory systems, preanalytic systems, analytic systems and postanalytic systems effectively to prevent potential problems from becoming quality issues.

Sources for this article: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CLIA Basic and Beyond Training Sept. 2006; National Laboratory Training Network Teleconference Jan. 19, 2006.

HOT TOPICS

Hot topics are areas of concern that have been discussed at CLIA conferences or have been found on surveys.

Proficiency Testing Rotation

- Include all personnel who perform the testing.
- Rotate events, not specimens (one individual should test all five specimens of an event; a second individual would test all five specimens of the next event).
- Use the primary instrument or method being used for patient testing.

Proficiency Testing Specimens Used for Competency Evaluation

- Use for competency **after** the results have been received.

Document the treatment and handling of proficiency testing specimens

- Date received and condition.
- Reconstitution date, time and by whom.
- Dilutions.
- Calculations.

Follow Manufacturer's Instructions

- Testing limitations (e.g., some mono tests are limited to those older than 18).
- Specimen preparation (e.g., some coagulation procedures require platelet-poor plasma).

Competency Evaluations

- All testing personnel must be evaluated for competency annually, including supervisors.

Verification of temperature requirements

- Check the manufacturer's temperature requirements and the actual storage temperature (e.g., freezer temperatures less than minus 20 degrees Celsius for certain supplies).

CAUTION: Are your INRs (International Normalization Ratios) accurate?

Please check your coagulation package inserts to ensure you are using the correct ISI (International Sensitivity Index) for your current lot number and instrumentation!

QUESTIONS AND ANSWERS (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q. What do I do if a laboratory sends referral specimens to my laboratory for analysis and I suspect they are proficiency specimens?

A. Notify CMS (Centers for Medicare and Medicaid Services) through the State CLIA Agency.

Q. What do I need to do if my laboratory changes director, location, ownership, certificate type, or accrediting agency?

A. Notify the State CLIA Agency within 30 days and send a completed CLIA application form (CMS-116).

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